Allison M. Brown
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Phone: (212) 735-3222
Fax: (917) 777-3222
Allison.Brown@skadden.com

Geoffrey M. Wyatt
(admitted *pro hac vice*)
Bradley A. Klein
(admitted *pro hac vice*)
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
Phone: (202) 371-7000
Geoffrey.Wyatt@skadden.com
Bradley.Klein@skadden.com

Abigail Hazlett
(admitted *pro hac vice*)
Michael A. Schwartz
(admitted *pro hac vice*)
Brian M. Nichilo
TROUTMAN PEPPER HAMILTON SANDERS LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, Pennsylvania 19103
Phone: (215) 981-4000
Fax: (215) 981-4750
Abigail.Hazlett@troutman.com
Michael.Schwartz@troutman.com
Brian.Nichilo@troutman.com

Attorneys for Defendant

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al., ex rel.* JESSICA PENELOW and CHRISTINE BRANCACCIO,	:	No. 12-cv-07758 (ZNQ) (LHG)
Plaintiffs,	:	
v.	:	
JANSSEN PRODUCTS, LP,	:	
Defendant.	:	

JANSSEN PRODUCTS, LP'S PROPOSED JURY INSTRUCTIONS

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I. INTRODUCTORY STATEMENT

Janssen Products, LP ("Janssen") respectfully submits the attached proposed jury instructions.

By submitting these instructions, Janssen does not waive any defenses or arguments, nor does it concede that there is any triable fact issue on any question pertaining to either liability or damages. Janssen maintains that it is entitled to a take-nothing judgment on all claims. Janssen reserves its rights to seek judgment as a matter of law, judgment notwithstanding the verdict, and any other appropriate relief before, during, or after trial. Janssen also reserves its rights to withdraw, amend, or add requested instructions at all times in advance of their submission to the jury, or to request corrections to any charge (proposed or otherwise) after it is given to the jury.

Dated: April 19, 2024

Respectfully submitted,

/s/ Allison M. Brown
Allison M. Brown
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Phone: (212) 735-3222
Fax: (917) 777-3222
Allison.Brown@skadden.com

II. PRELIMINARY INSTRUCTIONS

Instruction No. 1. 3d Cir. Model Civ. Jury Instrs. § 1.1 (2020)
(Introduction; Role of Jury)

Now that you have been sworn, I have the following preliminary instructions for your guidance as jurors in this case.

You will hear the evidence, decide what the facts are, and then apply those facts to the law that I will give to you.

You and only you will be the judges of the facts. You will have to decide what happened. I play no part in judging the facts. You should not take anything I may say or do during the trial as indicating what I think of the evidence or what your verdict should be. My role is to be the judge of the law. I make whatever legal decisions have to be made during the course of the trial, and I will explain to you the legal principles that must guide you in your decisions. You must follow that law whether you agree with it or not.

Instruction No. 2. Sources Cited
(Description of Case; Summary of Applicable Law)

This is a False Claims Act case. The False Claims Act is a law that allows the federal government to recover money when it has been defrauded. This law also allows private citizens to sue on behalf of the government to recover the government's money. The private citizens who bring the lawsuit are called Relators. In this case, Relators Jessica Penelow and Christine Brancaccio claim that Janssen, a pharmaceutical company, defrauded the government. Janssen denies those claims.[1]

I will give you detailed instructions on the law at the end of the case, and those instructions will control your deliberations and decision. But in order to help you follow the evidence, I will now give you a brief summary of the elements that Relators must prove to make their case.

Relators say that Janssen violated the federal False Claims Act in two different ways, which the Court and the parties refer to as the "Promotional Claims" and the "Speaker Claims." I will describe each of them to you now.

Promotional Claims: Relators first contend that Janssen violated the False Claims Act by allegedly falsely promoting HIV medications Prezista and Intelence,

[1] Based on 3d Cir. Model Civ. Jury Instrs. § 1.2 (2020), modified and expanded to fit this case.

allegedly causing doctors to prescribe these medications to government-insured HIV-positive patients, which then allegedly caused the government to pay for Prezista and Intelence prescriptions that the government would not have paid for otherwise because the prescriptions were made for uses that are not covered by Medicare. These are Relators' "Promotional Claims."

Janssen denies that it falsely promoted Prezista or Intelence. Janssen maintains that it promoted Prezista and Intelence for its approved uses, that is, as HIV medications to treat HIV-positive patients, and in ways that were widely accepted. Moreover, Janssen maintains that doctors made prescribing decisions based on their own professional medical judgment, and the government paid for Prezista and Intelence prescriptions that aligned with government policies and treatment guidelines.

To prevail on their Promotional Claims, Relators must prove each of the following essential elements:

First, Janssen caused doctors to write a Prezista or Intelence prescription that was ultimately submitted to Medicare as a claim for reimbursement; and

Second, the claim for reimbursement of the Prezista or Intelence prescription was false; and

Third, the falsity in the claim for reimbursement was material to the government's decision to pay the claim; and

Fourth, Janssen knew that the claim for reimbursement of the Prezista or Intelence prescription was false.[2]

Speaker Claims: Relators next allege that Janssen violated the federal Anti-Kickback Statute and False Claims Act by paying doctors who served as speakers on speaker programs designed to educate other doctors about Prezista and Intelence. According to Relators, these payments were unlawful because they were intended to induce the speakers to prescribe Prezista and Intelence or reward them for doing so. These are Relators' "Speaker Claims."

Janssen denies that it improperly paid doctors. Janssen maintains that it paid doctors for them to speak to other doctors and healthcare professionals about the benefits of Prezista and Intelence, the amounts paid were reasonable and within industry standards, and that it was lawful and proper for Janssen to use its speaker programs to try to influence doctors and other healthcare providers who attended speaker programs to prescribe Prezista or Intelence.

[2] *See* "Count I: False Claims Act (Promotional Claims)" and related substantive instructions below for further details.

To prevail on their Speaker Claims, Relators must first prove that Janssen violated the Anti-Kickback Statute. Specifically, Relators must prove:

First, Janssen paid money—including any kickback or bribe—to doctors;

Second, the payments were intended to induce the doctors who were speakers to prescribe Prezista and Intelence;

Third, those prescriptions were paid for by Medicare; and

Fourth, Janssen acted knowingly and willfully with respect to each of these elements. That is, Janssen knew its conduct was unlawful and intended to do something that the law forbids.

If Relators prove that Janssen violated the Anti-Kickback Statute, Relators must then prove that the claims submitted to a government health insurance program for a Prezista or Intelence prescription resulted from a violation of the Anti-Kickback Statute, and that this violation was material to the government's decision to pay the claim.[3]

[3] *See* "Count II: False Claims Act (Speaker Claims) – Falsity (AKS)" and related substantive instructions below for further details.

Instruction No. 3. 3d Cir. Model Civ. Jury Instrs. § 1.3 (2020)
(Conduct of Jury)

Now, a few words about your conduct as jurors.

First, I instruct you that during the trial and until you have heard all of the evidence and retired to the jury room to deliberate, you are not to discuss the case with anyone, not even among yourselves. If anyone should try to talk to you about the case, including a fellow juror, bring it to my attention promptly. There are good reasons for this ban on discussions, the most important being the need for you to keep an open mind throughout the presentation of evidence. I know that many of you use cell phones, smart phones, and other portable electronic devices; laptops, netbooks, and other computers both portable and fixed; and other tools of technology, to access the internet and to communicate with others. You also must not talk to anyone about this case or use these tools to communicate electronically with anyone about the case. This includes your family and friends. You may not communicate orally with anyone about the case on your cell phone, smart phone, or portable or fixed computer or device of any kind; or use these devices to communicate electronically by messages or postings of any kind including e-mail, instant messages, text messages, text or instant messaging services, or through any blog, website, internet chat room, or by way of any other social networking websites or services.

If any lawyer, party, or witness does not speak to you when you pass in the hall, ride the elevator, or the like, remember it is because they are not supposed to talk or visit with you, either.

Second, do not read or listen to anything related to this case that is not admitted into evidence. By that I mean, if there is a newspaper article or radio or television report relating to this case, do not read the article or watch or listen to the report. In addition, do not try to do any independent research or investigation on your own on matters relating to the case or this type of case. Do not do any research on the internet, for example. You are to decide the case upon the evidence presented at trial. In other words, you should not consult dictionaries or reference materials, search the internet, websites, blogs, or use any other electronic tools to obtain information about this case or to help you decide the case. Please do not try to find out information from any source outside the confines of this courtroom.

Again, do not reach any conclusion on the claims or defenses until all of the evidence is in. Keep an open mind until you start your deliberations at the end of the case.

Instruction No. 4. 3d Cir. Model Civ. Jury Instrs. § 1.4 (2020)
(Bench Conferences)

During the trial it may be necessary for me to talk with the lawyers out of your hearing by having a bench conference. If that happens, please be patient.

We are not trying to keep important information from you. These conferences are necessary for me to fulfill my responsibility, which is to be sure that evidence is presented to you correctly under the law.

We will, of course, do what we can to keep the number and length of these conferences to a minimum.

I may not always grant an attorney's request for a conference. Do not consider my granting or denying a request for a conference as any indication of my opinion of the case or of what your verdict should be.

Instruction No. 5. 3d Cir. Model Civ. Jury Instrs. § 1.5 (2020)
(Evidence)

The evidence from which you are to find the facts consists of the following:

1. The testimony of the witnesses;

2. Documents and other things received as exhibits;

3. Any facts that are stipulated—that is, formally agreed to by the parties.

The following things are not evidence:

1. Statements, arguments, and questions of the lawyers for the parties in this case;

2. Objections by lawyers.

3. Any testimony I tell you to disregard; and

4. Anything you may see or hear about this case outside the courtroom.

You must make your decision based only on the evidence that you see and hear in court. Do not let rumors, suspicions, or anything else that you may see or hear outside of court influence your decision in any way.

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever

weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

There are rules that control what can be received into evidence. When a lawyer asks a question or offers an exhibit into evidence, and a lawyer on the other side thinks that it is not permitted by the rules of evidence, that lawyer may object. This simply means that the lawyer is requesting that I make a decision on a particular rule of evidence. You should not be influenced by the fact that an objection is made. Objections to questions are not evidence. Lawyers have an obligation to their clients to make objections when they believe that evidence being offered is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it. If the objection is sustained, ignore the question. If it is overruled, treat the answer like any other. If you are instructed that some item of evidence is received for a limited purpose only, you must follow that instruction.

Also, certain testimony or other evidence may be ordered struck from the record and you will be instructed to disregard this evidence. Do not consider any testimony or other evidence that gets struck or excluded. Do not speculate about what a witness might have said or what an exhibit might have shown.

Instruction No. 6. 3d Cir. Model Civ. Jury Instrs. § 1.6 opt.2 (2020)
(Direct and Circumstantial Evidence)

There are two types of evidence that you may use in reaching your verdict. One type of evidence is called "direct evidence." An example of "direct evidence" is when a witness testifies about something that the witness knows through his own senses—something the witness has seen, felt, touched or heard or did. If a witness testified that he saw it raining outside, and you believed him, that would be direct evidence that it was raining. Another form of direct evidence is an exhibit where the fact to be proved is its existence or current condition.

The other type of evidence is circumstantial evidence. "Circumstantial evidence" is proof of one or more facts from which you could find another fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

You should consider both kinds of evidence that are presented to you. The law makes no distinction in the weight to be given to either direct or circumstantial evidence. You are to decide how much weight to give any evidence.

Instruction No. 7. 3d Cir. Model Civ. Jury Instrs. § 1.7 (2020)
(Credibility of Witnesses)

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You are the sole judges of the credibility of the witnesses. "Credibility" means whether a witness is worthy of belief. You may believe everything a witness says or only part of it or none of it. In deciding what to believe, you may consider a number of factors, including the following:

(1) the opportunity and ability of the witness to see or hear or know the things the witness testifies to;

(2) the quality of the witness's understanding and memory;

(3) the witness's manner while testifying;

(4) whether the witness has an interest in the outcome of the case or any motive, bias or prejudice;

(5) whether the witness is contradicted by anything the witness said or wrote before trial or by other evidence;

(6) how reasonable the witness's testimony is when considered in the light of other evidence that you believe; and

(7) any other factors that bear on believability.

The weight of the evidence to prove a fact does not necessarily depend on the number of witnesses who testify. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves.

Instruction No. 8. 3d Cir. Model Civ. Jury Instrs. § 1.8 (2020)
(Jury Questions for Witnesses)

Only the lawyers and I are allowed to ask questions of witnesses. You are not permitted to ask questions of witnesses.

Instruction No. 9. 3d Cir. Model Civ. Jury Instrs. § 1.9 opt. 2 (2020)
(Note-Taking by Jurors)

As you see, we have a court reporter here who will be transcribing the testimony during the course of the trial. But you should not assume that the transcripts will be available for your review during your deliberations. You must pay close attention to the testimony as it is given.

You may not take notes during the course of the trial. There are several reasons for this. It is difficult to take notes and, at the same time, pay attention to what a witness is saying and the witness's manner while testifying. One of the reasons for having a number of persons on the Jury is to gain the advantage of your individual and collective memories so that you can then deliberate together at the end of the trial and reach agreement on the facts. While some of you might feel comfortable taking notes, other members of the Jury may not feel as comfortable and may not wish to do so. Notes might be given too much weight over memories, especially the memories of those who do not take notes. So, for those reasons, I ask that you not take notes during the trial.

Instruction No. 10. 3d Cir. Model Civ. Jury Instrs. § 1.10 (2020) (Preponderance of the Evidence)

This is a civil case. Relators are the parties who brought this lawsuit. Janssen is the party against whom the lawsuit was filed. Relators have the burden of proving their case by what is called a preponderance of the evidence. That means Relators have to prove to you, in light of all the evidence, that what they claim is more likely so than not so. To say it differently: if you were to put the evidence favorable to Relators and the evidence favorable to Janssen on opposite sides of the scales, Relators would have to make the scales tip to their side. If Relators fail to meet this burden, you must find for Janssen and against Relators. If you find after considering all the evidence that a claim or fact is more likely so than not so, then the claim or fact has been proved by a preponderance of the evidence.

In determining whether any fact has been proved by a preponderance of evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

You may have heard of the term "proof beyond a reasonable doubt." That is a stricter standard of proof and it applies only to criminal cases. It does not apply in civil cases such as this. So you should put it out of your mind.

Instruction No. 11. 3d Cir. Model Crim. Jury Instrs. § 1.19 (2021) (Corporate Responsibility)

The defendant Janssen is a corporation. A corporation is a legal entity that may act only through individuals who are called its agents. The agents of a corporation are its officers, directors, employees, and other persons who are authorized by the corporation to act for it.

You must give to a corporate defendant the same impartial consideration of the evidence that you would give to any individual.

The legal responsibility of a corporation, if any, is based on the conduct of its agents. To find Janssen liable under the False Claims Act, you will need to find that the Relators proved that each of the essential elements of each claim was committed by an employee or some other agent of Janssen and that this person committed those elements within the course and scope of his or her employment or agency and that this person committed those elements with the intent to benefit Janssen.

This is only a preliminary outline of corporate responsibility. At the end of the trial, I will give you final instructions on corporate responsibility and on other

matters of law. Those final instructions will be more detailed; they will guide you in reaching your verdict in this case.[4]

[4] Language modified to reflect the fact that this is a civil case.

Instruction No. 12. 3d Cir. Model Civ. Jury Instrs. § 1.12 (2020) (Description of Trial Proceedings)

The trial will proceed in the following manner:

First, an attorney for Relators will make an opening statement to you. Next, an attorney for Janssen will make an opening statement. What is said in the opening statements is not evidence, but is simply an outline to help you understand what each party expects the evidence to show.

After the attorneys have made their opening statements, then each party is given an opportunity to present its evidence.

Relators go first because they have the burden of proof. Relators will present witnesses whom counsel for Janssen may cross-examine, and Relators may also present evidence. Following Relators' case, Janssen may present evidence. Counsel for Relators may cross-examine witnesses for the defense. After the parties' main case is presented, they may be permitted to present what is called rebuttal evidence.

After all the evidence has been presented, the attorneys will present to you closing arguments to summarize and interpret the evidence in a way that is helpful to their clients' positions. As with opening statements, closing arguments are not evidence. Once the closing arguments are completed, I will then instruct you on

the law. After that you will retire to the jury room to deliberate on your verdict in this case.[5]

[5] Modified to omit duplicative statement about instructions on the law in light of statement of case instruction above, and to reflect fact that parties will give opening statements.

III. GENERAL INSTRUCTIONS FOR USE AT TRIAL

Instruction No. 13. 3d Cir. Model Civ. Jury Instrs. § 2.4 (2020) (Stipulation of Fact)

The parties have stipulated that certain facts are true, and those stipulations have been read to you during this trial. You must therefore treat these facts as having been proved for the purposes of this case.

Instruction No. 14. 3d Cir. Model Civ. Jury Instrs. § 2.5 (2020) (Use of Deposition)

A deposition is the sworn testimony of a witness taken before trial. The witness is placed under oath and swears to tell the truth, and lawyers for each party may ask questions. A court reporter is present and records the questions and answers.

The deposition of [name of witness], which was taken on [date], is about to be [has been] presented to you [by a video] [by reading the transcript]. Deposition testimony is entitled to the same consideration and is to be judged, insofar as possible, in the same way as if the witness had been present to testify.

Instruction No. 15. 3d Cir. Model Civ. Jury Instrs. § 2.7 (2020)
(Charts and Summaries in Evidence)

[Name of party] has presented exhibits in the form of charts and summaries. I decided to admit these charts and summaries in place of the underlying documents that they represent in order to save time and avoid unnecessary inconvenience. You should consider these charts and summaries as you would any other evidence.

Instruction No. 16. 3d Cir. Model Civ. Jury Instrs. § 2.8 (2020)
(Charts and Summaries Not Admitted in Evidence)

Certain charts and summaries that have not been received in evidence have been shown to you in order to help explain or illustrate the contents of books, records, documents, testimony, or other evidence in the case. [Describe the charts and summaries that have not been admitted.] These charts and summaries are not themselves proof of any facts. They are not binding on you in any way. If they do not correctly reflect the facts shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the evidence.

Instruction No. 17. 3d Cir. Model Civ. Jury Instrs. § 2.11 (2020) (Opinion Testimony)

You have heard [will hear] testimony containing opinions from [name of witness]. In weighing this opinion testimony, you may consider [his/her] qualifications, the reasons for [his/her] opinions, and the reliability of the information supporting those opinions, as well as the factors I have previously mentioned for weighing the testimony of any other witness. The opinion of [name of witness] should receive whatever weight and credit, if any, you think appropriate, given all the other evidence in the case.

In deciding whether to accept or rely upon the opinion of [name of witness], you may consider any bias that [name of witness] may have, including any bias that may arise from evidence that [name of witness] has been or will be paid for reviewing the case and testifying [or from evidence that [name of witness] testifies regularly and makes a large portion of [his/her] income from testifying in court].

Instruction No. 18. 3d Cir. Model Civ. Jury Instrs. § 2.13 (2020)
(Transcript of Audio-Recorded Conversation)

At this time you are going hear a conversation that was recorded. This is proper evidence for you to consider. Please listen to it very carefully. I am going to allow you to have a transcript of the recording to help you identify speakers and as a guide to help you listen to the recording. If you believe at any point that the transcript says something different from what you hear on the recording, remember it is the recording that is the evidence, not the transcript. Any time there is a variation between the recording and the transcript, you must be guided solely by what you hear on the recording and not by what you see in the transcript.

Instruction No. 19. 3d Cir. Model Civ. Jury Instrs. § 2.14 (2020) (Recess Admonition)

We are about to take our first recess and I remind you of the instruction I gave you earlier. During this recess and any other recess, you must not discuss this case with anyone, including your fellow jurors, members of your family, people involved in the trial, or anyone else. If anyone tries to talk to you about the case, do not tell your fellow jurors but tell me about it immediately. Do not read, watch or listen to any news reports of the trial, or conduct any research or investigation, including on the Internet. Remember that I told you not to use any electronic tools to communicate with anyone about the case or to do research relating to the case. Finally, remember to keep an open mind until all the evidence has been received and you have heard the views of your fellow jurors.

If you need to speak with me about anything, simply give a signed note to [identify court personnel] to give to me.

I will not repeat these admonitions each time we recess or adjourn, but you will be reminded of them on occasion.

Instruction No. 20. 3d Cir. Model Civ. Jury Instrs. § 1.12 (2020)
(Role of Jury—End of the Case)

Members of the jury, you have seen and heard all the evidence and the arguments of the attorneys. Now I will instruct you on the law. You have two duties as a jury. Your first duty is to decide the facts from the evidence in the case. This is your job, and yours alone. Your second duty is to apply the law that I give you to the facts. You must follow these instructions, even if you disagree with them. Each of the instructions is important, and you must follow all of them. Perform these duties fairly and impartially. Do not allow sympathy, prejudice, fear, or public opinion to influence you. Nothing I say now, and nothing I said or did during the trial, is meant to indicate any opinion on my part about what the facts are or about what your verdict should be.[6]

[6] Third Circuit Model Civil Jury Instructions § 1.1 cmt. (2020).

IV. COUNT I: FEDERAL FALSE CLAIMS ACT (PROMOTIONAL CLAIMS)

Instruction No. 21. Sources Cited (Overview of Medicare Part D)

Before I explain the law that applies to Relators' claims, I am going to explain to you how the Medicare program that is at issue in this case works, so you can understand how claims are made and how those claims result in payments by the government.

Relators' allegations concern Medicare Part D. Medicare Part D is an optional prescription drug benefit for Medicare-eligible individuals, which generally means individuals who are age 65 or older or who have a qualifying disability (which does not include an HIV diagnosis).[7] Part D benefits are provided through private plan providers that are called "Part D plan sponsors."[8]

Part D plan sponsors create formularies—or lists—of covered drugs that must comply with certain Medicare requirements.[9] With respect to HIV specifically, CMS, the federal government entity that administers Medicare,

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[7] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4197 (Jan. 28, 2005) (describing Part D); CMS, *Getting Started with Medicare*, https://www.medicare.gov/basics/get-started-with-medicare ("Medicare is health insurance for people 65 or older.").

[8] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4197 (Jan. 28, 2005).

expects that Part D plan sponsors' formularies will accommodate national guidelines and offer complete treatment.[10] HIV medications are designated as a "protected class" of medications, and CMS requires prescription-drug plans to cover "all or substantially all" FDA-approved HIV medications.[11]

Drugs are eligible for Part D coverage and reimbursement by Medicare if they are used for medically accepted indications.[12] "Medically accepted indication" refers to the diagnosis or medical condition for which a drug is being

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[10] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4260 (Jan. 28, 2005) ("We are looking to existing national standards to inform our review at the drug level, and Part D plans will be expected to accommodate national guidelines and offer complete treatment options for a variety of medical conditions, including . . . HIV.").

[11] *See* CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 30.2.5 (rev. 2015), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ch%206%20%2801-30-2015%29.pdf; *Janssen Prods.*, 2021 WL 6052425, at *6-7 (stating in "Undisputed Material Facts" that "Under the Part D Statute, antiretroviral medications are designated as a 'protected class of drugs,' and the government requires Part D plans to cover 'all or substantially all' FDA-approved antiretroviral medications . . . ." (citations omitted)).

[12] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4197 (Jan. 28, 2005). Janssen maintains its objection to this requirement because, contrary to CMS's conclusion, the Medicare statute does not limit coverage to medically accepted indications. *See Layzer v. Leavitt*, 770 F. Supp. 2d 579 (S.D.N.Y. 2011). This instruction is proposed subject to that objection.

prescribed, not the dose being prescribed.[13] Under Medicare, Part D plan sponsors have the flexibility to determine whether the definition of "medically accepted indication" is met with regard to the particular use of a drug.[14]

It is the responsibility of Part D plan sponsors—not pharmaceutical companies, doctors or pharmacists—to ensure that covered Part D drugs are prescribed for a medically accepted indication and therefore eligible for coverage and reimbursement under Medicare Part D.[15] Pharmacists are not required to contact each physician to verify whether a prescription is being used for a

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[13] CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2015) ("[M]edically-accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication.").

[14] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4228-29 (Jan. 28, 2005) ("Plans have the flexibility to decide how to monitor whether a drug is prescribed for a medically accepted indication, as well as to determine whether the statutory definition of 'medically accepted indication' is met with regard to the particular use of a drug.").

[15] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4229 (Jan. 28, 2005) ("It will be Part D plans' responsibility to ensure that covered Part D drugs are prescribed for a medically accepted indication; plans may, for example, rely on utilization management policies and procedures (which we will review as part of our comprehensive review of Part D plan benefits) to ensure that drugs are prescribed and used for medically accepted indications."); CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2015) ("Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications . . . .").

medically accepted indication.[16] And doctors have no obligation to document or justify prescriptions that are not for medically accepted indications.[17]

The medically accepted indications for a drug that are eligible for Medicare reimbursement may include off-label uses. CMS has acknowledged the value of prescribing for off-label uses (that is, uses that do not have FDA approval).[18] CMS recognizes that off-label use is critically important and may be the mainstay of medical practice for successfully managing certain conditions, including HIV/AIDS.[19]

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[16] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4229 (Jan. 28, 2005) ("We clarify that pharmacists will not be required to contact each physician to verify whether a prescription is being used for other than a medically accepted indication."); CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2015) ("Dispensing pharmacists are not required to contact each prescriber to verify a prescription is being used for a medically-accepted indication").

[17] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005) (disclaiming intent to establish "new documentation requirement for prescribers" with respect to off-label prescriptions).

[18] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005) ("We recognize the value of off label prescribing, particularly with regard to certain medical conditions.").

[19] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4260 (Jan. 28, 2005) ("In actuality, off-label use is critically important and may be the mainstay of medical practice for successfully managing certain conditions, such as mental illnesses, chronic pain, chronic heart failure, arthritis, Parkinson's, HIV/AIDS and dementia.").

Accordingly, Part D plan sponsors may cover prescriptions for off-label uses of FDA-approved drugs, provided that the FDA has not made a determination that the drug is unsafe for that use.[20] And Part D plan sponsors may also (but are not required to) offer supplemental benefits, including for drugs that are excluded from Part D coverage.[21] Part D plan sponsors also may exclude from coverage drugs that are not reasonable and necessary for the diagnosis or treatment of illness or injury, but are not required to do so.[22]

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[20] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005) ("Further, we clarify that the USP model guidelines would not preclude Part D sponsors from assigning an FDA approved drug to a category or class based on an off label use for that drug, provided the FDA has not made a determination that the drug is unsafe for that use.").

[21] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4197 (Jan. 28, 2005) (describing the provision of supplemental benefits through enhanced alternative coverage); *id.* at 4473 ("Medicare Part D allows PDPs and MA-PDs to provide drugs that are specifically excluded from being Part D drugs if they do so as supplemental benefits through enhanced alternative coverage. We believe that some beneficiaries with chronic conditions will choose to enroll in Part D plans that offer enhanced alternative coverage.").

[22] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4230 (Jan. 28, 2005) (explaining that "a Part D plan may exclude from coverage covered Part D drugs for which payment may not be made under section 1862(a) of the Act if applied to Part D," i.e., "items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, except those vaccines identified in section 1862(a)(1)(B) of the Act as covered Part B vaccines"); CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 20.4 (rev. 2015) ("[A] Part D sponsor may exclude from qualified prescription drug coverage any Part D drug . . . [f]or which payment would not be made if items and services are not

It is Part D plan sponsors—not pharmaceutical companies, doctors, or pharmacists—that submit claims for and receive payments from the federal government for prescription drug coverage.[23] When a doctor writes a prescription and it is filled at a pharmacy, the pharmacy submits the prescription information to the Part D plan sponsor, which determines if the prescription is covered by Medicare or otherwise eligible for coverage under its benefits plan, pays for the prescription, and submits claims for reimbursement from the Medicare program. Reimbursement payments from Medicare are made to Part D plan sponsors based on their costs for drugs they cover under their Part D plans.[24]

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reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").

[23] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4306 (Jan. 28, 2005).

[24] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4306 (Jan. 28, 2005).

Instruction No. 22. Sources Cited
(Overview of Promotional Claims)

As I mentioned at the beginning of the trial, Relators claim Janssen violated the federal False Claims Act in two separate ways, which will be referred to as the Promotional Claims and the Speaker Claims. I am now going to explain the law that applies to Relators' Promotional Claims.

For the Promotional Claims, Relators contend that Janssen violated the federal False Claims Act when it allegedly falsely promoted HIV medications Prezista and Intelence. Relators claim the alleged false promotional practices caused doctors to prescribe these medications to government-insured HIV-positive patients, which thereby allegedly caused the submission of claims for payment to Part D plan sponsors, and caused Part D plan sponsors to cover Prezista and Intelence prescriptions that they would not have paid for otherwise, which then caused the Part D plan sponsors to submit claims to Medicare for reimbursement for these prescriptions, which Relators claim were not eligible for Medicare coverage. For you to find Janssen liable under the False Claims Act for the

Promotional Claims, Relators must prove by a preponderance of the evidence each of the following essential elements:[25]

First, for each prescription and claim for reimbursement at issue, you must find that Janssen engaged in false promotional practices, and that those practices **caused** a doctor to write that particular prescription for Prezista or Intelence, and further that those practices caused such prescriptions to be submitted to and covered by Part D plan sponsors, which then caused the Part D plan sponsors to submit claims for reimbursement for the prescriptions to CMS;

Second, you must find that the claim for reimbursement of the Prezista or Intelence prescription at issue was **false**;

Third, you must find that the falsity in the claim for reimbursement at issue was **material** to the CMS's decision to pay for the Prezista or Intelence prescription; and

Fourth, you must find that Janssen **knew** that the claim for reimbursement of the Prezista or Intelence prescription at issue was false.

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[25] *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) ("A False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality.").

Relators must prove all four of these elements separately for each claim for reimbursement that they are challenging.[26] If Relators prove all four elements for some prescriptions or claims for reimbursement and not others, Janssen can only be held liable for the prescriptions and claims for reimbursement as to which all four elements are proven.

I will now explain each essential element in more detail.

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[26] *See United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 714 (7th Cir. 2014) ("At best, a reasonable jury might be able to say that *some* of [defendant's] claims were false. But that is not enough to satisfy relators' burden of proof. Of course, the relators' difficulty in coming forward with evidence in supporting even an approximate finding regarding how many of [defendant's] claims were false may be partly attributed to [defendant's] wrongdoing. But, under the FCA, the plaintiff must 'prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.' A defendant's wrongdoing does not shift the burden of proof to the defendant under the FCA.") (quoting 31 U.S.C. § 3731(d)).

A. Causation

Instruction No. 23. Sources Cited
(Promotional Claims—Causation)

First, for each prescription and claim for reimbursement at issue, Relators must prove causation by a preponderance of the evidence. That means that Relators must prove that Janssen engaged in false promotional practices, that those practices caused the doctor to write that particular prescription for Prezista or Intelence, and further that those practices caused the prescription at issue to be submitted to a Part D plan sponsor and caused the Part D plan sponsor to cover the prescription and submit a claim to CMS for reimbursement for that prescription.

To prove that false promotion was a cause of a prescription and submission of a claim for reimbursement, Relators must prove that the prescribing doctor would not have made the same prescribing decision—and no claim for the prescription of Prezista or Intelence would have been submitted to or covered by a Part D plan sponsor, or ultimately reimbursed by Medicare—had Janssen not engaged in false promotional conduct.[27] Further, Relators must show that the false

[27] *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 491 (3d Cir. 2017) (but-for causation is necessary but not sufficient to prove causation); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004) (explaining "this Court applie[s] ordinary causation principles from negligence law in determining responsibility under the FCA" and, therefore, defendant's conduct must be "a substantial factor in bringing about" the filing of a false claim) (quoting

promotional conduct they allege was integral to the decision to submit a false claim for payment or reimbursement to Medicare.[28]

Restatement (Second) of Torts § 443); Restatement (Second) of Torts § 432 (general rule is that "the actor's negligent conduct is not a substantial factor in bringing about the harm to another if the harm would have been sustained even if the actor had not been negligent," and the general rule applies except in cases where "two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself is sufficient to bring about harm to another"); Dkt. 75, at 6 (statement by United States that what would give rise to an FCA claim is proof that a defendant "induc[ed] physicians to prescribe a drug when they would not do so otherwise").

[28] *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 491 (3d Cir. 2017) (noting that "the causation element cannot be met merely by showing 'but for' causation") (citation omitted); *see id.* (citing *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006) for the proposition that the false claim must be "*integral* to a causal chain leading to payment").

Instruction No. 24. Source Cited
(Promotional Claims—Causation—Factors to Consider as to Doctor)

In determining whether Relators have proven that a doctor would not have made the same prescribing decision had Janssen not engaged in false promotional conduct, you should consider the other facts that might inform a doctor's prescribing decision; whether any false promotional conduct by Janssen created a force or series of forces which are in continuous and active operation up to the time of the doctor's decision; and the lapse of time between any false promotional conduct and the prescription at issue.[29]

[29] *See* Restatement (Second) of Torts § 433 ("The following considerations are in themselves or in combination with one another important in determining whether the actor's conduct is a substantial factor in bringing about harm to another: (a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it; (b) whether the actor's conduct has created a force or series of forces which are in continuous and active operation up to the time of the harm, or has created a situation harmless unless acted upon by other forces for which the actor is not responsible; (c) lapse of time.").

Instruction No. 25. Sources Cited
(Promotional Claims—Causation—Fact of Off-Label Prescribing Not Conclusive)

Doctors can prescribe medications for both uses that the FDA has approved and uses that the FDA has not approved based on the medical circumstances of each individual case and the doctors' professional judgment.[30]

Pharmaceutical companies are not permitted to provide doctors information that is false or misleading. But it is legal for pharmaceutical companies to provide information that is not included in a medication's label, including, for example, off-label studies, provided that the information is truthful and non-misleading.[31]

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[30] *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012) ("Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs."); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) ("Prescription drugs frequently have therapeutic uses other than their FDA-approved indications. . . . Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses.").

[31] *See Caronia*, 703 F.3d at 168-69 ("Our conclusion is limited to FDA-approved drugs for which off-label use is not prohibited, and we do not hold, of course, that the FDA cannot regulate the marketing of prescription drugs. We conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 229 (S.D.N.Y. 2015) ("[I]f the speech at issue is found truthful and non-misleading, under *Caronia*, it may not serve as the basis for a misbranding action."); Jury Instructions at 9, Dkt. 434, *United States v. Facteau*, No. 15-cr-10076 (D. Mass. filed July 21, 2016) ("Off-label promotion refers to promoting a device for an off-label use, meaning an intended use that has not been

And a statement about information not included in a medication's label need not be conclusively established for it to be truthful and non-misleading. Rather, statements that represent fair inferences drawn from the data, even if those inferences are subject to debate, constitute truthful speech that is protected by the First Amendment.[32]

CMS recognizes the value and existence of off-label prescribing.[33] It has specifically acknowledged that off-label use is critically important and may be the mainstay of medical practice for managing certain conditions, including HIV.[34]

FDA-cleared or approved. It is not illegal in and of itself for a device manufacturer to provide truthful, not misleading information about an off-label use. The FDCA does not prohibit or criminalize truthful, not misleading off-label promotion. You may not convict the defendant of a crime based solely on truthful, non-misleading statements promoting [an] FDA-cleared or approved device, even if the use being promoted is not a cleared or approved use. Over the course of this trial you've heard evidence about a number of statements, marketing claims, and other communications about the [device at issue]. It is up to you to decide whether a statement is truthful and non-misleading or whether it is false and misleading.").

[32] *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 497 (2d Cir. 2013) (holding that "a statement [that] is made as part of an ongoing scientific discourse about which there is considerable disagreement" is protected opinion, regardless whether the opposing party "alleges that the inferences drawn from those data were the wrong ones").

[33] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005) ("We recognize the value of off label prescribing, particularly with regard to certain medical conditions.").

[34] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4260 (Jan. 28, 2005) ("In actuality, off-label use is critically important and may be the mainstay of medical practice for successfully managing

Therefore, you may not conclude, based solely on the mere fact that certain prescriptions submitted for reimbursement were for off-label indications, that statements by Janssen caused a doctor to write such a prescription or caused a Part D plan sponsor to submit a claim to Medicare for reimbursement for such a prescription.

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certain conditions, such as mental illnesses, chronic pain, chronic heart failure, arthritis, Parkinson's, HIV/AIDS and dementia.").

Instruction No. 26. Source Cited
(Promotional Claims—Causation—Factors to Consider as to Part D Plan)

In determining whether Relators have proven that any improper conduct by Janssen caused a false claim to be submitted and caused CMS to reimburse the claim, you may consider the role of Part D plan sponsors in the claim submission process.

As I explained to you, Part D plan sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically accepted indications, and may rely on tools such as utilization management policies and procedures to do so.[35] They may also conduct consultations with physicians regarding treatment options and outcomes.[36] Part D plan sponsors are the entities that ultimately receive payment from Medicare, and to do so they are the ones charged with submitting prescription information to support their claims for reimbursement.[37]

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35 CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2015).

36 CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 30.2.5 (rev. 2015) (noting with respect to "HIV/AIDS drugs" in particular that "Part D sponsors may conduct consultations with physicians regarding treatment options and outcomes in all cases").

37 CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4306-07 (Jan. 28, 2005).

CMS does not require pharmacists to contact each prescriber to verify whether a prescription is being used for a medically accepted indication.[38] And CMS has stated that doctors have no obligation to document or justify prescriptions that are not for medically accepted indications.[39]

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[38] CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2015).

[39] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005) (disclaiming intent to establish "new documentation requirement for prescribers" with respect to off-label prescriptions).

B. Falsity

Instruction No. 27. Sources Cited (Promotional Claims—Falsity)

In addition to proving causation, Relators also must prove by a preponderance of the evidence that each claim asking the government to pay or provide reimbursement for a Prezista or Intelence prescription for an HIV-positive patient was false.[40]

Relators' claim in this case is that Janssen's conduct ultimately caused Part D plan sponsors to submit claims to CMS for reimbursement for Prezista and Intelence prescriptions that were false because those claims were not for medically accepted indications.

As I explained to you, Medicare covers medications that are prescribed for medically accepted indications.[41] "Medically accepted indication" refers to the

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[40] "[O]ur cases instruct that FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." *United States ex rel. Druding v. Care Alternatives, Inc.*, 952 F.3d 89, 97 (3d Cir. 2020).

[41] *See United States ex rel. Dickson v. Bristol-Meyers Squibb Co.*, 123 F. Supp. 3d 584, 605 (D.N.J. 2015) (explaining that Medicare provides coverage for prescriptions for "medically accepted indications") (quoting 42 U.S.C. § 1396r-8(k)(6)). Janssen preserves its position that an FDA-approved drug is covered by Medicare Part D regardless of indication, *see Layzer v. Leavitt*, 770 F. Supp. 2d 579, 587 (S.D.N.Y. 2011), and without need to show that a prescription was reasonable and necessary (a requirement that a Part D sponsor "may" require, 42 U.S.C. § 1395w-102(e)(3)(A), but for which there is no evidence of such a

diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication.[42]

CMS charges Part D plan sponsors with the responsibility for ensuring that covered Part D drugs are prescribed for medically accepted indications.[43] As part of that responsibility, Part D plan sponsors have the flexibility to determine whether the definition of "medically accepted indication" is met with regard to the particular use of a drug.[44] Part D plan sponsors also make the determination

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requirement for HIV treatment in this case (*see* Schafermeyer Dep. 70:21-74:23)). Janssen does not submit and will object to any instruction as to state-law requirements. The rules under the various state Medicaid and ADAP programs are distinct. Indeed, states have the discretion to cover drugs prescribed for something other than a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i). Thus, it was incumbent upon Relators to establish state-law requirements and show that the Promotional Claims, even if proven, would establish that false claims were submitted under state law. *See*, *e.g.*, *United States ex rel. Banignan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 295 (D. Mass. 2012) (state FCA claims failed as a matter of law where relators did not establish that off-label prescriptions would not be paid by state Medicaid programs at issue). Relators have not done so, and they therefore cannot prove these claims at trial.

[42] CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2015) ("[M]edically-accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication.").

[43] *See* CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2015) ("Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications.").

[44] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4228-29 (Jan. 28, 2005) ("Plans have the flexibility to decide how to monitor whether a drug is prescribed for a medically accepted indication, as

whether to deny coverage of a drug because it is unreasonable or unnecessary for the diagnosis or treatment of illness or injury, but they need not deny coverage on this basis.[45]

Therefore, Relators must prove by a preponderance of the evidence that each Prezista or Intelence prescription was falsely represented by a Part D plan sponsor to CMS to be eligible for reimbursement under Medicare when it was not, and thus that the claim for reimbursement for each such prescription was "false."

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well as to determine whether the statutory definition of 'medically accepted indication' is met with regard to the particular use of a drug.").

[45] CMS, Final Rule, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4230 (Jan. 28, 2005) (explaining that "a Part D plan may exclude from coverage covered Part D drugs for which payment may not be made under section 1862(a) of the Act if applied to Part D," i.e., "items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, except those vaccines identified in section 1862(a)(1)(B) of the Act as covered Part B vaccines"); CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 20.4 (rev. 2015) ("[A] Part D sponsor may exclude from qualified prescription drug coverage any Part D drug . . . [f]or which payment would not be made if items and services are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").

Instruction No. 28. Sources Cited
(Promotional Claims—Falsity—Fraud Not Presumed)

Fraud is never presumed, but must always be proved by a preponderance of the evidence. You should assume persons are fair and honest in their dealings until the contrary appears from the evidence. If a transaction called into question is equally capable of two interpretations, one honest and the other fraudulent, it should be found to be honest.[46]

[46] 3 Fed. Jury Prac. & Instr. § 123:10 (6th ed.).

C. Materiality

Instruction No. 29. Sources Cited (Promotional Claims—Materiality)

The third element that Relators must prove by a preponderance of the evidence is that the falsity in a claim for reimbursement was material to CMS's decision to pay the claim.

For the False Claims Act, "material" means having a natural tendency to influence, or be capable of influencing, the government's payment decision.[47] The focus of the materiality question is on the government's payment decision; it is distinct from the causation question I have instructed you on, which focuses on what influence any alleged false promotion had on doctors, Part D plan sponsors, and others. Thus, when considering materiality, you should consider what CMS would have done if it knew the claims for reimbursement were false in the ways Relators allege.[48]

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[47] *See Petratos*, 855 F.3d at 489 ("[T]he False Claims Act defines [materiality] as 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money.'") (quoting 31 U.S.C. § 3729(b)(4)).

[48] *See In re Plavix Mktg.*, 332 F. Supp. 3d at 949 (explaining that allegations about a defendant's "conduct in marketing [a drug] to physicians in a fraudulent or misleading manner, allegedly inducing those physicians to submit prescriptions for [the drug] to Medicaid, go to how the [allegedly false] claim makes its way to the government and therefore are considered under the causation analysis," and that the "[m]ateriality analysis begins after a claim has been submitted") (citation omitted); *Petratos*, 855 F.3d at 491 ("By attempting to focus our inquiry solely on

The materiality standard is demanding.[49] Materiality cannot be found where the falsity is minor or insubstantial.[50] And falsity is not material merely because eligibility for reimbursement is a condition of payment, or because CMS would have the option to decline to pay if it knew the prescriptions were allegedly not eligible for reimbursement.[51] The question is what CMS would have done; thus, a

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the physician's materiality determination, Petratos again tries to pass off restyled causation arguments as proof of materiality. The alleged fraud's effect on physicians is relevant to the extent that it caused claims eventually to reach CMS.").

[49] *See Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016) ("The materiality standard is demanding.").

[50] *See Universal Health Servs.*, 579 U.S. at 194 ("Materiality . . . cannot be found where noncompliance is minor or insubstantial"); *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (holding certain data submitted with claims for reimbursement to CMS were "minor or insubstantial misstatements where [m]ateriality . . . cannot be found") (internal quotations omitted).

[51] *See Petratos*, 855 F.3d at 489 ("[A] misrepresentation is not material 'merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment . . . [or because] the Government would have the option to decline to pay if it knew of the defendant's noncompliance.'") (citation omitted); *see also In re Plavix Mktg.*, 332 F. Supp. 3d at 947 ("[T]he mere fact that a drug being 'reasonable and necessary' was a condition of payment, without more, does not establish materiality[.]") (citing *Petratos*, 855 F.3d at 490); *United States ex rel. Lampkin v. Pioneer Educ., LLC*, No. 16-1817 (RMB/KMW), 2020 U.S. Dist. LEXIS 136022 (D.N.J. July 31, 2020), at *11 (holding relator merely identified a condition of payment but did not sufficiently allege the government payor "would have ceased payment . . . if it learned about any, or all" of the alleged violations).

misrepresentation is not material when the government would have paid the claims with full knowledge of the alleged falsity.[52]

Proof of materiality can include evidence that CMS administrators consistently refuse to pay for HIV medications prescribed to HIV-positive patients that were allegedly not eligible for reimbursement for the reasons Relators allege.[53]

On the other hand, if CMS administrators pay for HIV medications for HIV-positive patients despite their actual knowledge that certain requirements were not met, that is evidence that those requirements are not material.[54] Or if CMS

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[52] *See Petratos*, 855 F.3d at 490 ("[A] misrepresentation is not 'material to the Government's payment decision,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance.") (emphasis omitted) (citing *Universal Health Services*, 579 U.S. at 181); *United States v. Bristol-Myers Squibb Co. (In re Plavix Mktg., Sales Practice & Prods Liab. Litig.)*, 332 F. Supp. 3d 927, 948 (D.N.J. 2017) ("[I]n the FCA specific context, *the government* is always the 'ultimate recipient of the misrepresentation' about compliance with a statutory, regulatory, or contractual requirement,' and materiality is judged exclusively in relation to the government's payment decision.") (citation omitted); *United States ex rel. Freedman v. Bayada Home Health Care, Inc.*, No. 3:19-cv-18753, 2021 WL 1904735, at *7 (D.N.J. May 12, 2021) (same).

[53] *See Petratos*, 855 F.3d at 489 ("Materiality may be found where 'the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.'") (quoting *Universal Health Servs.*, 579 U.S. at 196); *United States ex rel. DiLello v. Hackensack Meridian Health*, No. 20-02949, 2022 WL 1284734, at *8 (D.N.J. Apr. 29, 2022) (same).

[54] *See United States ex rel. Druding v. Care Alternatives, Inc.*, 81 F.4th 361, 374-75 (3d Cir 2023) (noting that the government's inaction over a period of years

administrators regularly pay for HIV medications for HIV-positive patients despite actual knowledge that certain requirements were not met, and have signaled no change in position, that is evidence that the requirements are not material.[55]

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is evidence of immateriality even if it was not dispositive under the facts of the case); *see also United States ex rel. Cressman v. Solid Waste Servs.*, No. CV 13-5693, 2018 WL 1693349, at *6 (E.D. Pa. Apr. 6, 2018) ("As in *Petratos*, the Department of Justice's declination to intervene or take any action against Defendant supports the conclusion that it does not consider the regulatory violation or failure to disclose asserted by Plaintiff to be 'material' . . . .'").

[55] *See Spay*, 875 F.3d at 763–64 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.") (quoting *Universal Health Servs.*, 579 U.S. at 195); *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 542 (10th Cir. 2020) (granting summary judgment on materiality where, among other reasons, "[t]o this day, CMS has done nothing in response and continues to pay [defendant's] Medicare claims" and "[a]lthough CMS may not have independently verified [defendant's] noncompliance – and thus may not have obtained 'actual knowledge' of the alleged infractions – its inaction in the face of detailed allegations from a former employee suggests immateriality").

Instruction No. 30. Sources Cited
(Promotional Claims—Materiality—Corporate Integrity Agreements)

You have heard evidence about corporate integrity agreements to which Janssen or its affiliate was subject. You may consider the requirements established by these agreements as relevant to what the government considers material when it comes to reimbursing payments for prescription drugs.[56] You may also consider Janssen's reporting under these agreements as evidence of what the government actually knew about the allegations in this case, and you may consider the fact that the government continued to reimburse prescriptions for Prezista and Intelence following Janssen's reporting as relevant to whether the government considered these allegations to be material to its decision to pay.[57]

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[56] Dkt. 330 at 15-16.

[57] *United States ex rel. Maur v. Hage-Korban*, 981 F.3d 516, 528-29 (6th Cir. 2020) (government monitoring of the defendant pursuant to a corporate integrity agreement addressing similar allegations was probative of its knowledge).

D. Knowledge

Instruction No. 31. Sources Cited (Promotional Claims—Knowledge)

The fourth element that Relators must prove by a preponderance of the evidence is that Janssen knew that each claim that it caused to be submitted was false. Janssen knew that the claim was false if Janssen had actual knowledge of, deliberately ignored, or recklessly disregarded the falsity of the claim.[58]

What matters for this purpose is what Janssen itself thought and believed. If Janssen held a belief that its conduct was lawful that proves to have been wrong based on an honest mistake, that is insufficient to charge Janssen with knowledge of false claims.[59] But it is not necessary for Relators to prove that Janssen acted with specific intent to defraud.[60]

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[58] *See* 31 U.S.C. § 3729(b)(1); *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175 (3d Cir. 2019) ("[T]he False Claims Act requires that the defendants know, deliberately ignore, or recklessly disregard *the falsity of their claim*. . . . The claims [in this case] are false because they allegedly violated the Stark Act. The question is whether the defendants at least recklessly disregarded that possibility.") (emphasis added).

[59] *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 751, 753 (2023) (explaining that the "FCA's standards focus primarily on what [the defendants] thought and believed" and indicating that an "honest mistake" does not establish scienter).

[60] *See* 31 U.S.C. § 3729(b)(1).

Instruction No. 32. 3d Cir. Model Crim. Jury Instrs. § 7.06 (2021) (Promotional Claims—Knowledge—Relevance of Employees' Knowledge)

In evaluating Janssen's knowledge for the Promotional Claims, you may conclude that Janssen knew of things known to its employees and other agents acting within the scope of their employment or agency if Janssen's corporate officers were actually informed of the things within its employees' or agents' knowledge, or if Janssen's corporate officers deliberately avoided learning those things or recklessly delegated responsibility for such things to its employees or agents.[61] In order to find that an act was committed within the scope of the employment or agency given to the employee or agent, the evidence must prove

[61] *See United States ex rel. Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.*, 5 F.4th 315, 349 (3d Cir. 2021) (holding that "[a]n entity's knowledge for FCA purposes may be imputed based on that of a particular employee or officer" where evidence supported the conclusion that a corporate vice president "recklessly delegated to unknowledgeable individuals the responsibility for ensuring that employees were properly classified") (citing *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1272-73 (D.C. Cir. 2010); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 919 (4th Cir. 2003)); *see also Sci. Applications. Int'l Corp.*, 626 F.3d at 1274-75 (acknowledging that officers can be held responsible for knowledge held by lower level employees where exercise of a "limited duty to inquire" would reveal such knowledge but rejecting a rule that would "draw[] no distinction between the knowledge of corporate officers and that of potentially thousands of ordinary employees").

that the act related directly to the general duties that the employee or agent was expected to perform by Janssen.[62]

Janssen is not charged with knowledge of anything known to its employees and other agents acting outside the scope of their employment or agency. An employee or agent was not acting within the scope of his or her employment or agency if that person performed an act which Janssen, in good faith, had forbidden the employee or agent to perform. A corporate defendant is not responsible for acts that it tries to prevent. However, a corporate defendant, like an individual defendant, may not avoid liability by meaningless or purely self-serving pronouncements.[63]

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62 Third Circuit Model Criminal Jury Instructions § 7.06 (2021) (modified).

63 Streamlined and modified to adapt to facts and civil context of the case.

Instruction No. 33. Sources Cited
(Promotional Claims—Knowledge—Corporate Integrity Agreements)

You have heard evidence about corporate integrity agreements to which Janssen or its affiliate was subject. You may consider the requirements established by these agreements as relevant to Janssen's knowledge of what the government considers to be lawful or unlawful conduct.[64] You may also consider Janssen's reporting of Relators' allegations under these agreements as probative of a lack of the knowledge and intent required under the False Claims Act.[65]

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64 Dkt. 330 at 15-16.

65 *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003) ("A contractor that is open with the government regarding problems and limitations and engages in a cooperative effort with the government to find a solution lacks the intent required by the Act." (citing *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 327 (9th Cir. 1995))).

V. COUNT II: FEDERAL FALSE CLAIMS ACT & ANTI-KICKBACK STATUTE (SPEAKER CLAIMS)

Instruction No. 34. Sources Cited
(Overview of Speaker Claims)

For the Speaker Claims, Relators allege that Janssen made payments to doctors to work as speakers to educate other doctors about Prezista and Intelence, and that Janssen violated the federal Anti-Kickback Statute and False Claims Act because it intended these payments to induce the speakers to prescribe Prezista and Intelence or to reward them for doing so.

To decide whether Janssen is liable under the False Claims Act for the Speaker Claims, you must first determine whether Janssen violated the Anti-Kickback Statute. If you find a violation of the Anti-Kickback Statute, you will then consider whether the payments you found to violate the statute resulted in one or more prescriptions for Prezista or Intelence being submitted for reimbursement by Medicare, and whether the payments were material to a CMS administrator's decision to pay the claim for reimbursement.

A. Falsity—AKS Violation

Instruction No. 35. Sources Cited
(Speaker Claims—Falsity (AKS Violation))

For you to find Janssen violated the Anti-Kickback Statute, Relators must prove by a preponderance of the evidence the following:

First, Janssen paid remuneration—including any kickback or bribe—to doctors who were speakers in its speaker programs;[66]

Second, the payments were made to induce the doctors who were speakers (not attendees of the program) to prescribe Prezista and Intelence;[67]

Third, prescriptions resulted from the improper payment and were paid for by Medicare;[68] and

Fourth, Janssen acted knowingly and willfully with respect to each of these elements.[69]

I will now explain some of these elements in further detail.

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66 42 U.S.C. § 1320a-7b(b)(2).

67 42 U.S.C. § 1320a-7b(b)(2)(B).

68 42 U.S.C. § 1320a-7b(g).

69 *See* 42 U.S.C. § 1320a-7b(b)(2); *see also United States ex rel. Gohil v. Sanofi U.S. Services Inc.*, 500 F. Supp. 3d 345, 359 (E.D. Pa. 2020) ("To establish that [defendant] violated the AKS, [relator] must prove that (i) the alleged schemes involved offering or paying 'remuneration'; (ii) at least one purpose of the schemes was to 'induce' doctors to prescribe more [of defendant's medication]; and (iii) [defendant] possessed the requisite scienter.").

1. Remuneration

Instruction No. 36. Sources Cited
(Speaker Claims—Falsity (AKS Violation)—Remuneration)

As used in this case, "remuneration" means a payment for services that exceeds the fair market value of those services. Doctors who serve as speakers perform a service for the benefit of the company that hires them, and in doing so they spend time that they otherwise could spend on other endeavors, including the performance of their primary job responsibilities. Fair compensation of doctors for time spent is not illegal and does not constitute "remuneration" under the Anti-Kickback Statute. Thus, to satisfy this element, Relators must prove to you that the compensation doctors received for speaking exceeded the fair market value for the services they rendered to Janssen.[70]

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[70] *United States ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 699 (N.D. Miss. 2012) ("[C]ourts use 'fair market value' as the gauge of value when assessing the remuneration element of the offense" under the AKS.); *see also United States ex rel. Chao v. Medtronic PLC*, No. 2:17-cv-01903-MCS-SS, 2021 WL 4816647, at *7-9 (C.D. Cal. Apr. 12, 2021) ("The importance of establishing fair market value is also established in guidelines set forth by the Office of the Inspector General for the Department of Health and Human Services . . . ."); HHS-OIG, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 23,731, 23,738 (May 5, 2003) (noting that "[p]harmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturer," and advising that setting "compensation [] at fair market value" helps ensure that such arrangements—including for "potentially beneficial" activities like "speaking"—do not pose a risk of abuse); *Bingham v. HCA, Inc.*, 783 F. App'x 868, 873 (11th

2. Inducement

Instruction No. 37. Sources Cited
(Speaker Claims—Falsity (AKS Violation)—Inducement)

As used in this case, "to induce" means an attempt to exercise influence over the judgment of the doctor who was paid as a speaker to cause the speaker to prescribe Prezista or Intelence.[71]

Mere payment to a speaker is not unlawful. The law permits Janssen to promote its medications by paying doctors to educate other doctors through speaker programs.[72] And it is lawful and proper for Janssen to use its speaker

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Cir. 2019) ("[T]he issue of fair market value is not limited to [the defendant's] safe harbor defense, as Relator suggests, but is rather something Relator must address in order to show that [the defendant] offered or paid remuneration . . . .").

[71] *See* Final Jury Instructions at 125, Dkt. 441, *United States ex rel. Cairns v. D.S. Medical, LLC*, No. 12-cv-00004, 2018 WL 4607839 (E.D. Mo. filed Dec. 8, 2017) ("'To induce' means an attempt to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.").

[72] *See United States ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) ("There was nothing illegal about paying physicians for their participation in [consultation and presentation] programs and there is no evidence that participation was conditioned upon prescribing [defendant's] drugs to Medicaid patients."); *Janssen Prods.*, 2021 WL 6052425, at *3 (noting in "Statement of Undisputed Facts" that "Janssen promoted Prezista and Intelence to physicians through . . . speaker programs" and that "[d]uring the Speaker programs, physicians educated other physicians about Prezista and Intelence").

programs to try to influence doctors and other healthcare providers who attend speaker programs to prescribe Prezista or Intelence.[73]

To prove inducement, it is also not enough for Relators to prove that Janssen hoped or expected or believed that a doctor who was paid as a speaker may prescribe Prezista or Intelence. Nor is it enough for Relators to prove that Janssen merely encouraged a doctor who was paid as a speaker to prescribe Prezista or Intelence.[74] Similarly, it does not suffice for Relators to prove that Janssen

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[73] *See United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1055-56 (C.D. Cal. 2016) ("Celgene did track the number [of prescriptions] written by attendees . . . , but if anything, that cuts against [relator's] argument that the speaker program was intended to influence the *speakers'* prescribing decisions. . . . [Additionally] [a]lthough there is evidence that the speaker program was intended to increase prescriptions of [Celgene's] drugs, there is no evidence that speakers did anything other than convey truthful scientific information about the drugs.") (citations omitted); *United States v. Pfizer, Inc.*, 188 F. Supp. 3d 122, 134-35 (D. Mass. 2016) ("It is likewise unremarkable that Pfizer tracked its return on investment from the [speaker] series; as a for-profit company, this is to be expected. It is noteworthy, however, that Pfizer did not track the prescriptions written by speakers, but rather the prescriptions written by attendees . . . . This fact directly refutes any accusation that the series was a sham meant to compensate prescribing speakers rather than pitch to prescribing attendees.").

[74] *See United States v. McClatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000) (finding district court "accurately informed the jury" that defendants "cannot be convicted [of violating the AKS] merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes" and "mere oral encouragement to refer patients or the mere creation of an attractive place to which patients can be referred does not violate the law") (emphasis omitted; citation omitted); *United States v. Holland*, 396 F. Supp. 3d 1210, 1239 (N.D. Ga. 2019) ("[T]o the degree that the Government argues the

selected speakers who were high prescribers of or had extensive prior experience with Prezista or Intelence.

Rather, Relators must prove that the speaker payment was a quid pro quo transaction, that is, one in which Janssen paid doctors to speak at its speaker programs in return for or as a reward for prescribing Prezista or Intelence.[75]

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one-purpose theory to the jury, it must properly account for Defendants' ability to legally enter into a business relationship with referring individuals or entities . . . .") (citing *McClatchey*, 217 F.3d at 834-35).

[75] *See* Final Jury Instructions at 5, Dkt. 244, *United States v. Reichel*, No. 15-cr-10324 (D. Mass. filed June 17, 2016) ("'Induce' in this context means to undertake to gain influence over the judgment of the physician making a decision regarding the prescription and order of drugs. More specifically, as charged in this indictment, the contemplated inducement must be what is referred to as a quid pro quo ('this for that') transaction, one in which a person pays for meals or gives speaker payments (the 'this') to a physician in exchange for the order or prescribing of [the company's] drugs (the 'that')."); *United States v. Krikheli*, 461 F. App'x 7, 11 (2d Cir. 2012) ("Here, the district court instructed the jury that . . . '[t]o induce a person means to attempt to gain influence over the reason or judgment of that person.' . . . [And] the prosecution had to prove 'that the remuneration was offered or paid as a quid pro quo in return for the referring of the patient.' . . . These instructions accurately described the law . . . .") (citations omitted).

3. Knowledge and Willfulness

Instruction No. 38. Sources Cited
(Speaker Claims—Falsity (AKS Violation)—Knowledge)

"Knowingly" means that Janssen was conscious and aware of the nature of its actions and of the surrounding facts and circumstances.[76] Innocent mistakes or mere negligence are not sufficient to establish that Janssen acted knowingly.[77]

In evaluating Janssen's knowledge for the Speaker Claims, you may conclude that Janssen knew of things known to its employees and other agents acting within the scope of their employment or agency if Janssen's corporate officers were actually informed of the things within its employees' or agents' knowledge, or if Janssen's corporate officers deliberately avoided learning those things or recklessly delegated responsibility for such things to its employees or agents.[78]

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[76] 3d Cir. Model Crim. Jury Instrs. § 5.02 (2018) (modified)

[77] *See id.* § 5.02 ("A person acts 'knowingly' if that person acts voluntarily and intentionally and not because of mistake or accident or other innocent reason.").

[78] *See United States ex rel. Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.*, 5 F.4th 315, 348-49 (3d Cir. 2021) (holding that "[a]n entity's knowledge for FCA purposes may be imputed based on that of a particular employee or officer" where evidence supported the conclusion that a corporate vice president "recklessly delegated to unknowledgeable individuals the responsibility for ensuring that employees were properly classified") (citing *United States v. Science Applications International Corp.*, 626 F.3d 1257, 1272-73 (D.C. Cir. 2010); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 919 (4th Cir. 2003)); *see also Sci. Applications Int'l Corp.*, 626 F.3d

In order to find that an act was committed within the scope of the employment or agency given to the employee or agent, the evidence must prove that the act related directly to the general duties that the employee or agent was expected to perform by Janssen.[79] Janssen is not charged with knowledge of anything known to its employees and other agents acting outside the scope of their employment or agency. An employee or agent was not acting within the scope of his or her employment or agency if that person performed an act which Janssen, in good faith, had forbidden the employee or agent to perform. A corporate defendant is not responsible for acts which it tries to prevent. However, a corporate defendant, like an individual defendant, may not avoid liability by meaningless or purely self-serving pronouncements.[80]

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at 1274-75 (acknowledging that officers can be held responsible for knowledge held by lower level employees where exercise of a "limited duty to inquire" would reveal such knowledge but rejecting a rule that would "draw[] no distinction between the knowledge of corporate officers and that of potentially thousands of ordinary employees") (citation omitted).

79 Third Circuit Model Criminal Jury Instructions § 7.06 (2021) (modified).

80 Third Circuit Model Criminal Jury Instructions § 7.06 (2021) (modified).

Instruction No. 39. Sources Cited
(Speaker Claims—Falsity (AKS Violation)—Willfulness)

"Willfully" means that Janssen knew its conduct was unlawful and intended to do something that the law forbids. That is, to find that Janssen acted willfully, you must find that Janssen acted with a purpose to disobey or disregard the law, or with a "vicious will."[81]

[81] Third Circuit Model Criminal Jury Instructions § 5.05 (2018) (modified); *see also Ruan v. United States*, 597 U.S. 450, 457 (2022) ("With few exceptions, 'wrongdoing must be conscious to be criminal.'") (citation omitted); *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 154-55 (2d Cir. 2024) (To be held liable under the AKS, a "defendant must act knowing that his conduct is unlawful, even if the defendant is not aware that his conduct is unlawful under the AKS specifically," which "accords with the general goal of criminal law to punish only those who act with a 'vicious will.'") (citation omitted).

Instruction No. 40. Sources Cited
(Speaker Claims—Falsity (AKS Violation)—Willfulness—Safe Harbor)

You should consider Janssen's belief that its speaker program complied with the law in deciding whether it acted willfully. As I explained, mere payments to doctors to serve as speakers are not unlawful. Rather, to be unlawful, the payments to speakers must be intended to induce those speakers to prescribe Prezista or Intelence

Additionally, payments are excluded from liability under the Anti-Kickback Statute if they comply with regulatory "safe harbors."[82] One such safe harbor covers personal services and management contracts. Under this safe harbor, a payment is permitted under the Anti-Kickback Statute and will not result in liability if the following requirements are met:

- The agreement is set out in writing and signed by the parties;
- The agreement covers all the services the speaker provides Janssen for the term of the agreement and specifies the services to be provided by the speaker;

[82] 42 CFR § 1001.952(d) (2007), https://www.govinfo.gov/content/pkg/CFR-2007-title42-vol4/pdf/CFR-2007-title42-vol4-sec1001-952.pdf.

- The agreement specifies the schedule of services rendered by the speaker and the length of and the charge for each speech or other service rendered;
- The term of the agreement is not less than one year;
- The aggregate compensation paid to the speaker over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare;
- The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
- The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Janssen's belief that its speaker payments were for a proper purpose or that its speaker program met the safe-harbor requirements would preclude a finding that it acted willfully as long as that belief was not reckless.

A belief is reckless if it is not only wrong under a reasonable reading of the law's requirements, but also shows that Janssen ran a risk of violating the law substantially greater than the risk associated with merely being careless.[83]

[83] *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 68-69 (2007); *cf. United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 754 (2023) (distinguishing *Safeco* from FCA cases, where only knowledge but not willfulness is required).

Instruction No. 41. Sources Cited
(Speaker Claims—Falsity (AKS Violation)—Willfulness—Employees)

In evaluating whether Janssen acted willfully, what matters is what Janssen thought or believed, not what the thoughts or beliefs of individual employees might have been. An employee's own belief that a practice was unlawful does not show that Janssen believed the same, even if the employee shared his or her belief with the Company.[84]

[84] *United States ex rel. Hart v. McKesson Corp.*, 96 F. 4th 145, 161 (2d Cir. 2024) (relator's belief that employer's business practice was unlawful was not evidence that employer "believed the same," even where the relator had allegedly "told his supervisor" about his views).

Instruction No. 42. Sources Cited (Speaker Claims—Falsity (AKS Violation)—Knowledge and Willfulness—Relevance of Government and Industry Practice)

In determining whether Janssen acted knowingly and willfully, you may consider Janssen's knowledge of the government's views, and the views of others in the pharmaceutical industry, on how to lawfully promote medications by paying doctors to educate other doctors through speaker programs.[85]

You also may consider whether Janssen's payments to doctors were in excess of fair market value, which may suggest that Janssen acted with requisite knowledge, or whether the payments were reasonable compensation for the

[85] *See* Order on Defendants' Motion to Compel Internal HHS-OIG Communications at 10, Dkt. 143, *United States v. Teva Pharms. USA, Inc.*, No. 20-cv-11548 (D. Mass. filed Jan. 25, 2023) ("The best evidence of Teva's scienter is its own documents and witnesses. In addition, it may seek, for example, discovery regarding other drug manufacturers' interpretation of the [government's special advisory bulletins]."); *United States ex rel. Hart v. McKesson Corp.*, No. 15-cv-0903, 2023 WL 2663528, at *11 (S.D.N.Y. Mar. 28, 2023) ("Other cases relied upon by [relator] involved distinct allegations that defendants were engaging in conduct that either violated internal policies prohibiting the specific conduct as unlawful under the AKS, or which was widely recognized within the industry as illegal."), *aff'd in part, vacated in part*, 96 F.4th 145 (2d Cir. 2024); *id.* ("OIG Advisory Opinions further indicated—at the time of [defendant's] alleged conduct here—that simply because a product or service has value does not necessarily mean that it violates the AKS.").

educational services the doctors provided on behalf of Janssen, which may suggest that Janssen did not act knowingly and willfully to disobey or disregard the law.[86]

[86] *See Celgene*, 226 F. Supp. 3d at 1054 ("The relevant question is whether Celgene's payments were excessive compared to the honoraria provided by other physician speaker programs."); *Purcell v. Gilead Scis., Inc.*, 439 F. Supp. 3d 388, 399 (E.D. Pa. 2020) ("The Office of Inspector General of the United States Department of Health and Human Services instructs many factors—such as whether a product manufacturer . . . pays a speaker in excess of the fair market value the speaker offers to the product manufacturer—may be considered to determine 'whether any one purpose of the [payment] may be, to induce or reward the referral or recommendation of business . . . .'") (alteration in original) (quoting *Compliance Program Guidance for Pharmaceutical Manufacturers*, U.S. Dep't of Health and Hum. Servs. Office of Inspector General (April 2003)); *Bingham v. HCA, Inc.*, 783 F. App'x 868, 873 (11th Cir. 2019) ("[T]he issue of fair market value is not limited to [defendant's] safe harbor defense, as Relator suggests, but is rather something Relator must address in order to show that [defendant] offered or paid remuneration to physician tenants.").

Instruction No. 43. Sources Cited
(Speaker Claims—Knowledge and Willfulness—Corporate Integrity Agreements)

You have heard evidence about corporate integrity agreements to which Janssen or its affiliate was subject. You may consider the requirements established by these agreements as relevant to Janssen's knowledge of what the government considers to be lawful or unlawful conduct.[87] You may also consider Janssen's reporting of Relators' allegations under these agreements as probative of a lack of the knowledge and willfulness required under the False Claims Act and Anti-Kickback Statute.[88]

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87 Dkt. 330 at 15-16.

88 *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003) ("A contractor that is open with the government regarding problems and limitations and engages in a cooperative effort with the government to find a solution lacks the intent required by the Act.") (citing *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 327 (9th Cir. 1995)).

B. Causation

Instruction No. 44. Sources Cited
(Speaker Claims—Causation)

If you find Relators proved by a preponderance of the evidence that Janssen violated the Anti-Kickback Statute, to find Janssen liable under the False Claims Act for the Speaker Claims, Relators must then prove by a preponderance of the evidence that a claim submitted to a government health insurance program for a Prezista or Intelence prescription resulted from a violation of the Anti-Kickback Statute.[89]

To prove that a claim submitted to a government health insurance program for a Prezista or Intelence prescription resulted from a violation of the Anti-Kickback Statute, Relators must prove that the doctor would not have prescribed Prezista or Intelence to the patient, and a claim would not have been submitted to a

[89] *See United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 98 (3d Cir. 2018) ("For a False Claims Act violation, [relator] must prove that at least one of [defendant's] claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute (as a kickback renders a subsequent claim ineligible for payment)."); 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act].").

government health insurance program for reimbursement, but for Janssen's payment to that doctor for conducting a speaker program.[90]

To prove a claim resulted from a violation of the Anti-Kickback Statute, it is not enough to show that Janssen's payment to a doctor for conducting a speaker program occurred close in time to the submission of a claim. Rather, Relators must prove a connection between Janssen's payment to a doctor and the subsequent submission of a claim for a Prezista or Intelence prescription.[91]

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[90] *See United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836 (8th Cir. 2022) ("[W]hen a plaintiff seeks to establish falsity or fraud through the 2010 amendment [to the AKS], it must prove that a defendant would not have included particular 'items or services' but for the illegal kickbacks.") (citation omitted), *rev'd*, 42 F.4th 828 (8th Cir. 2022); *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052 (6th Cir. 2023) ("When it comes to violations of the Anti-Kickback Statute, only submitted claims 'resulting from' the violation are covered by the False Claims Act. The ordinary meaning of 'resulting from' is but-for causation.") (citations omitted). Janssen acknowledges that the Third Circuit concluded that something less than but-for causation is required under the version of the AKS as amended in 2010 in *Greenway*, but respectfully submits that this conclusion was erroneous, as both *Cairns* and *Martin* hold. Janssen would be happy to provide additional briefing on this issue if it would be of assistance to the Court.

[91] *See Greenfield*, 880 F.3d at 100 ("Because any kickback violation is not eligible for reimbursement, to certify otherwise violates the False Claims Act. Yet there must be some connection between a kickback and a subsequent reimbursement claim. It is not enough . . . to show temporal proximity between [defendant's] alleged kickback plot and the submission of claims for reimbursement. . . . [Relator] must show, at a minimum, that at least one of the 24 federally insured patients for whom [defendant] provided services and submitted reimbursement claims was exposed to a referral or recommendation of [defendant]

by [recipient of defendant's charitable contributions] in violation of the Anti-Kickback Statute.").

C. Materiality

Instruction No. 45. Sources Cited (Speaker Claims—Materiality)

If you find Relators proved by a preponderance of the evidence that Janssen violated the Anti-Kickback Statute, to find Janssen liable under the False Claims Act for the Speaker Claims, Relators must also prove by a preponderance of the evidence that the falsity in the claims submitted to a government health insurance program was material to the government's decision to pay the claim.[92]

The same considerations that apply to the materiality element of Relators' Promotional Claims apply to this element of their Speaker Claims. Thus, for example, materiality cannot be found for falsity that is minor or insubstantial,[93] and falsity is not material merely because eligibility for reimbursement is a condition of payment, or because CMS would have the option to decline to pay if it knew the

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92 *See Greenfield*, 880 F.3d at 98 n.8 ("Even if [relator] proves that one of [defendant's] claims sought reimbursement for medical care that was provided in breach of the [Anti-Kickback] Statute, he must also satisfy the False Claims Act's materiality requirement, as falsity and materiality are distinct requirements in this context.").

93 *See Universal Health Servs.*, 579 U.S. at 194 ("Materiality . . . cannot be found where noncompliance is minor or insubstantial"); *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (holding certain data submitted with claims for reimbursement to CMS were "'minor or insubstantial misstatements where '[m]ateriality . . . cannot be found'") (citation omitted).

prescriptions were allegedly not eligible for reimbursement.[94] A misrepresentation is not material when the government would have paid the claims with full knowledge of the alleged falsity.[95]

Failure to comply with government or industry guidance on pharmaceutical company speaker programs is not sufficient to prove materiality.[96] Rather, you

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[94] *See Petratos*, 855 F.3d at 489 ("[A] misrepresentation is not material 'merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment . . . [or because] the Government would have the option to decline to pay if it knew of the defendant's noncompliance.'") (second alteration in original) (citation omitted); *see also In re Plavix Mktg.*, 332 F. Supp. 3d at 947 ("[T]he mere fact that a drug being 'reasonable and necessary' was a condition of payment, without more, does not establish materiality") (citing *Petratos*, 855 F.3d at 490); *United States ex rel. Lampkin v. Pioneer Educ., LLC*, No. 16-1817 (RMB/KMW), 2020 WL 4382275 (D.N.J. July 31, 2020), at *5 (holding relator merely identified a condition of payment but did not sufficiently allege the government payor "would have ceased payment . . . if it learned about any, or all" of the alleged violations).

[95] *See Petratos*, 855 F.3d at 490 ("[A] misrepresentation is not 'material to the Government's payment decision,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance.") (citing *Universal Health Services*, 579 U.S. at 181); *In re Plavix Mktg.*, 332 F. Supp. 3d at 948 (D.N.J. 2017) ("[I]n the FCA specific context, *the government* is always the 'ultimate recipient of the misrepresentation' about compliance with a statutory, regulatory, or contractual requirement,' and materiality is judged exclusively in relation to the government's payment decision.") (citation omitted); *United States ex rel. Freedman v. Bayada Home Health Care, Inc.*, No. 3:19-cv-18753, 2021 WL 1904735, at *7 (D.N.J. May 12, 2021) (same).

[96] *See Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916, 931 (E.D. Pa. 2019) ("The core of the [Supreme Court's] *Allina* decision as it relates to this case is that because the reimbursement standard applicable to the Phase 1 claims was contained in agency manuals that had not been promulgated pursuant to notice and

must decide whether Relators proved that CMS administrators would not have paid for the Prezista and Intelence prescriptions at issue had they known the prescriptions resulted from a violation of the Anti-Kickback Statute.[97]

comment, as required by the Medicare Act, Defendant could not have violated the FCA."), *vacated as moot*, 17 F.4th 376, 382 n.4 (3rd Cir. 2021).

[97] *See Petratos*, 855 F.3d at 490 ("[A] misrepresentation is not 'material to the Government's payment decision,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance.") (citing *Escobar*, 579 U.S. at 181); *In re Plavix Mktg.*, 332 F. Supp. 3d at 948 (D.N.J. 2017) ("[I]n the FCA specific context, *the government* is always the 'ultimate recipient of the misrepresentation' about compliance with a statutory, regulatory, or contractual requirement,' and materiality is judged exclusively in relation to the government's payment decision.") (citation omitted); *United States ex rel. Freedman v. Bayada Home Health Care, Inc.*, No. 3:19-cv-18753, 2021 WL 1904735, at *7 (D.N.J. May 12, 2021) (same).

VI. COUNTS I AND II: GOOD FAITH

Instruction No. 46. Sources Cited (Good Faith)

A violation of the False Claims Act requires proof that Janssen acted knowingly. A violation of the Anti-Kickback Statute requires proof that Janssen acted knowingly and willfully. If you find that Janssen acted in good faith, that would be a complete defense to an alleged violation, because good faith on Janssen's part would be inconsistent with its acting knowingly or willfully.

A person or a company acts in good faith when he, she, or it has an honestly held belief, opinion, or understanding about the existence of a fact or in the truth of statements, even though the belief, opinion, or understanding turns out to be inaccurate or incorrect. Therefore, in this case, if Janssen made an honest mistake or had an honest misunderstanding about the existence of a fact or in the truth of statements then it did not act knowingly or willfully.

Janssen does not have the burden of proving good faith. Good faith is a defense because it is inconsistent with the requirement of the False Claims Act and Anti-Kickback Statute that Janssen acted knowingly and willfully. As I have told you, it is the Relators' burden to prove by a preponderance of the evidence each element of the False Claims Act and each element of the Anti-Kickback Statute, including the elements regarding Janssen's mental state. In deciding whether the

Relators proved that Janssen acted knowingly and willfully, or, instead, whether Janssen acted in good faith, you should consider all of the evidence presented in the case that may bear on Janssen's state of mind. If you find from the evidence that Janssen acted in good faith, or if you find for any other reason that the Relators have not proved by a preponderance of the evidence that Janssen acted knowingly or willfully, you must find Janssen is not liable under the False Claims Act for the Promotional Claims or the Speaker Claims.[98]

[98] Third Circuit Model Criminal Jury Instructions § 5.07 (2018) (modified); *see United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 751, 753 (2023) (explaining that the "FCA's standards focus primarily on what [the defendants] thought and believed" and indicating that an "honest mistake" does not establish scienter).

VII. COUNTS I AND II: DAMAGES

Instruction No. 47. Sources Cited (Damages)

If you find that the Relators proved by a preponderance of the evidence that Janssen violated the federal False Claims Act for the Promotional Claims and/or the Speaker Claims, you must determine the damages, if any, the government suffered.[99] Of course, you should not interpret the fact that you are receiving instructions about damages as an indication either that you should find a violation of the False Claims Act or that you should award damages.

In this case, the measure of damages is the difference between the amount of money the government paid for false claims for Prezista and Intelence prescriptions and the value of what the government actually received.[100]

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[99] *See United States ex rel. Landis v. Tailwind Sports Corp.*, 292 F. Supp. 3d 211, 214-15 (D.D.C. 2017) ("[I]n a False Claims Act case the jury's 'instruction is to return a verdict for actual damages, for which the court alone then determines any multiplier, just as the court alone sets any separate penalty.'") (citation omitted).

[100] *See Sci. Applications Int'l Corp.*, 626 F.3d at 1279 (where government alleged company's invoices for consulting services were false because the company had failed to abide by the contract's conflict-of-interest provision, court stated that the "fact-finder bases damages on the amount the government actually paid minus the value of the goods or services the government received or used"); *United States ex rel. Landis v. Tailwind Sports Corp.*, 234 F. Supp. 3d 180, 200-01 (D.D.C. 2017) (where government-sponsored cycling team's invoices were allegedly false because the team concealed its violations of the sponsorship agreements' anti-doping provisions, court held "the government's actual damages

The purpose of awarding damages under the False Claims Act is to make the United States whole.[101] Damages, if any, must be fair compensation for the government's losses, no more and no less.[102] Damages are not allowed as a punishment and cannot be imposed or increased to penalize Janssen.

You should not award any damages for speculative harm, but only for harm that Relators have proven by a preponderance of the evidence that Janssen caused the government to suffer.[103] Because of the complexity of the question of

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(if any) [were] the difference between 'the amount the government paid' . . . minus what the defendants' services 'were worth to the government' as measured by 'the value of the . . . services the government received or used'") (quoting *Science Applications International Corp.*, 626 F. 3d at 1279); *see also United States ex rel. Davis v. District of Columbia*, 679 F.3d 832, 839-40 (D.C. Cir. 2012), 679 F.3d at 839-40 (holding that "[t]he government got what it paid for and there are no damages" in an FCA case involving false claims for Medicaid-reimbursable transportation services for special education students).

101 *See United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 923 (4th Cir. 2003) ("[A]n important purpose of the FCA . . . is to make the government completely whole.") (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551–52 (1943)).

102 *See United States ex rel. Davis v. District of Columbia*, 679 F.3d 832, 839 (D.C. Cir. 2012) ("False Claims Act damages are meant to 'put[ ] the government in the same position as it would have been if the defendant's claims had not been false'") (alteration in original) (quoting *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1278 (D.C. Cir. 2010)).

103 *See United States v. Luce*, 873 F.3d 999, 1013-14 (7th Cir. 2017) ("[E]ach of these four circuits has adopted the common-law understanding of foreseeable, or proximate, causation with respect to the imposition of liability *and* damages under the FCA.") (citing, among others, *United States v. Hibbs*, 568 F.2d 347 (3d Cir. 1977)) (emphasis added); *Science Applications*, 626 F.3d at 1278 (holding the

damages, Relators' burden is to prove damages with expert evidence. You must consider such expert evidence as presented to you and either credit it or reject it. You are not free to decide on a different damages amount that is not supported by an expert opinion.[104] In other words, even if you find that a false claim has been submitted, if the Relators have failed to present sufficient evidence from which to calculate damages, then the Relators have not satisfied their burden and no damages should be awarded.[105]

If you decide to award any damages to the United States, most of those damages will go to the United States. However, as provided by the False Claims

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government can only receive "the full value of payments made to the defendant . . . where the government *proves* that it received no value from the product [or service] delivered") (emphasis added); *United States ex rel. Wall v. Circle C Constr., LLC*, 813 F.3d 616, 617 (6th Cir. 2016) (holding actual damages are calculated by determining "whether the government in fact got less than it bargained for").

[104] *See Pitre v. City of New York*, No. 18 CIV. 5950 (DC), 2023 WL 7304991, at *4 (S.D.N.Y. Nov. 6, 2023) ("Generally, a plaintiff must provide an expert where damages 'are not the product of a simple mathematical calculation.'") (citation omitted).

[105] *Harrison*, 352 F.3d at 922-23 (affirming award of zero damages even though FCA liability had been established because relator "presented no evidence" of damage to the government); Final Jury Instructions at 21, Dkt. 161, *United States v. Sci. Applications Int'l Corp.*, No. 04-cv-1543 (D.D.C. filed Feb. 5, 2009) ("A showing of measurable damages to the United States is not an essential element for a cause of action under the False Claims Act.").

Act, the court may award a portion of any damages that you find in this case to the Relators, up to 30% of the damages awarded.[106]

[106] *See* 31 U.S.C. § 3730(d)(2) ("If the Government does not proceed with an action . . . the person brining the action . . . shall receive an amount which the court decides is reasonable . . . . The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action . . . and shall be paid out of such proceeds."); *see also Landis*, 292 F. Supp. 3d at 215 (citing *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, No. 95-1231, 2007 WL 851868, at *1 (D.D.C. Mar. 14, 2007) ("[T]he fact that relator has a significant financial interest in this litigation is fair game for cross-examination, as it pertains to relator's potential bias.")).

VIII. COUNTS I AND II: NUMBER OF FALSE CLAIMS

Instruction No. 48. Sources Cited (Number of False Claims)

If you find that the Relators proved by a preponderance of the evidence that Janssen violated the False Claims Act for the Promotional Claims and/or the Speaker Claims, you must then identify the number of false claims that Relators proved that Janssen caused to be submitted to CMS for payment. There will be a space in the verdict form for you to place the number of false claims Relators proved by a preponderance of the evidence, should you find that Janssen violated the False Claims Act.[107]

Of course, you should not interpret the fact that you are receiving instructions about identifying the number of false claims as an indication either that you should find a violation of the False Claims Act or that you should find that false claims were submitted.

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[107] *See, e.g.*, Final Jury Instructions at 20-21, Dkt. 161, *United States v. Sci. Applications Int'l Corp.*, No. 04-cv-1543 (D.D.C. filed Feb. 5, 2009) ("[Y]ou must determine the number of false or fraudulent claims that [defendant] presented to the United States government. . . . It is your duty to tally the number of false or fraudulent claims . . . for which you find [defendant] liable. There will be a space in the verdict form for you to place this number should you find for the government on the False Claims Act claims.").

IX. DELIBERATIONS

Instruction No. 49. 3d Cir. Model Civ. Jury Instrs. § 3.1 (2020) (Deliberations)

When you retire to the jury room to deliberate, you may take with you these instructions and the exhibits that the Court has admitted into evidence. You should select one member of the jury as your foreperson. That person will preside over the deliberations and speak for you here in open court.

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way.

Your second duty is to take the law that I give you, apply it to the facts, and decide if, under the appropriate burden of proof, the parties have established their claims. It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not let any bias, sympathy or prejudice that you may feel toward one side or the other influence your decision in any way.

As jurors, you have a duty to consult with each other and to deliberate with the intention of reaching a verdict. Each of you must decide the case for yourself, but only after a full and impartial consideration of all of the evidence with your fellow jurors. Listen to each other carefully. In the course of your deliberations, you should feel free to re-examine your own views and to change your opinion based upon the evidence. But you should not give up your honest convictions about the evidence just because of the opinions of your fellow jurors. Nor should you change your mind just for the purpose of obtaining enough votes for a verdict.

When you start deliberating, do not talk to the jury officer, to me or to anyone but each other about the case. During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as a cell phone, smart phone, or computer of any kind; the internet, any internet service, or any text or instant messaging service; or any internet chat room, blog, website, or social networking service, to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict.

You may not use these electronic means to investigate or communicate about the case because it is important that you decide this case based solely on the evidence presented in this courtroom. Information on the internet or available

through social media might be wrong, incomplete, or inaccurate. Information that you might see on the internet or on social media has not been admitted into evidence and the parties have not had a chance to discuss it with you. You should not seek or obtain such information and it must not influence your decision in this case.

If you have any questions or messages for me, you must write them down on a piece of paper, have the foreperson sign them, and give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you.

One more thing about messages. Never write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that a certain number is voting one way or another. Your votes should stay secret until you are finished.

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, each juror must agree to the verdict. Your verdict must be unanimous.

A form of verdict has been prepared for you. It has a series of questions for you to answer. You will take this form to the jury room and when you have

reached unanimous agreement as to your verdict, you will fill it in, and have your foreperson date and sign the form. You will then return to the courtroom and your foreperson will give your verdict. Unless I direct you otherwise, do not reveal your answers until you are discharged. After you have reached a verdict, you are not required to talk with anyone about the case unless I order you to do so.

Once again, I want to remind you that nothing about my instructions and nothing about the form of verdict is intended to suggest or convey in any way or manner what I think your verdict should be. It is your sole and exclusive duty and responsibility to determine the verdict.[108]

[108] Modified to remove references to notes and to Blackberries.

CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2024, a true and correct copy of the foregoing Defendant Janssen Products, LP's proposed jury instructions were served upon all counsel of record via the Court's Electronic Case Filing (ECF) system.

/s/ *Allison M. Brown*
Allison M. Brown